supporting structural member and graft member are formed from a metal or metal-like material metal or metal-like material.

25. (New) The implantable medical stent-graft according to Claim 24, wherein the metal or metal-like material is selected from the group consisting of titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, zirconium-titanium-tantalum alloys, nitinol, and stainless steel.---

REMARKS

Interview Summary

The Applicant respectfully thanks the Examiner for the telephonic interview between the Examiner and Applicant's attorney, Thomas S. Kim (Reg. No. 51,009), on March 30, 2003. During the interview, the Examiner and Mr. Kim discussed some of the advantages of the present invention over the cited art, including the monolithic nature of the plurality of laminate layers and the metal or metal-like composition of the graft, alone or as part of a graft-stent embodiment that patentably distinguish Applicant's invention over the prior art. The following arguments reflect these advantages, which the Examiner acknowledged and instructed Mr. Kim to highlight in the present response.

Preliminary Remarks

The Applicant respectfully thanks the Patent Office for determining that claims 14 and 15 would be allowable upon amending to stand as an independent claim. The Applicant has cancelled claim 2, 7, 19 and 20, while amending claims 1, 11 and 16. Also, the Applicant has added claims 21-25 in the present response.

The amendments and new claims presented herein are fully supported by the original specification and do not constitute new matter. The limitation "the plurality of laminated layers forms a substantially monolithic structure" in claim 1, and claims depending therefrom, is supported throughout the specification. In particular, this element of the claimed invention can be found discussed in the last paragraph of page 14 and the second paragraph of page 26 of the specification. The "biocompatible metal or metal-like material" in claims 22 and 24, and claims

depending therefrom, is supported throughout the specification. In particular, this element of the claimed invention can be found discussed in the first paragraph of page 7, ". . . a graft member is formed as a discrete thin sheet or tube of biocompatible metals or metal-like material." Also, the third paragraph on page 8 discloses a "stent-graft formed entirely of a metal or metal-like material." Accordingly, the Applicant respectfully requests entry and consideration of the pending claims.

Arguments

The Rejection of Claims 1-13 and 16-20 under 102(a) and (e) Over the Cited Art Should be Withdrawn

As discussed with the Examiner in an earlier telephonic interview with the undersigned attorney, the claims, as amended, are directed towards novel devices either formed of a "plurality of laminated layers form[ing] a substantially monolithic structure" or a graft member formed from a "metal or metal-like material." Such devices are not disclosed in the cited art as suggested by the Patent Office and, therefore, allowance is respectfully requested.

Contrary to the position of the Patent Office, both Sogard et al. (US Pat. No. 6,139,573) and Lentz et al. (US Pat. No. 5,961,545) fail to disclose, and therefore do not anticipate, all elements of the present claims. The disclosure in Sogard et al. is limited to a stent device formed of laminate layers consisting of a polymeric coating about an expandable stent. See Abstract of Sogard et al. Similarly, Lentz et al. discloses a device related to a graft, as part of the laminate structure, that is formed of a "porous expanded polytetrafluoroethylene." See Field of Invention section. On the other hand, the present claims are directed to devices that are either "substantially monolithic structures" or have a graft layer formed of a "metal or metal-like material." In particular, Sogard et al. is limited to "adhering, laminating, or otherwise bonding a fusible polymeric layer on either side of an open intermediate component and fusing the layers together. . . ." Col. 7, ln. 52-54. Whereas in Lentz, the tubes formed of polymeric material are laminated together by fusing the layers. Col. 5, ln. 1-2. Both Sogard and Lentz, in contrast to the present invention, simply do not disclose either of these elements of the present claims.

Furthermore, the cited art fails to teach or suggest the present invention. Firstly, the Sogard et al. discusses polymeric layers on either side of a stent, preferably expanded polytetrafluoroethylene. Col. 8, ln. 10-13. This polymeric layer forms the laminate system

along with the disclosed stent. This fails to suggest either a laminate structure that is substantially monolithic or a device including a graft formed of a metal or metal-like material. There is nothing disclosed to suggest a "substantially monolithic structure" because the Sogard teaches forming the device by adhering layers unlike the present invention, which is fabricated by metal deposition methodologies as used in microelectronics and non-fabrication vacuum coating arts. Page 21, ln. 2-5 of specification. Similarly, Lentz et al. fails to teach any fabrication method besides the method of securement or fusion. One of ordinary skill, upon review of Sogard or Lentz and the fabrication methods taught therein, would not be able to produce the present invention, a "monolithic one-piece construction of a device which yields a minimized device profile and cross-sectional area." Page 26, ln. 12-13 of specification. This monolithic one-piece construction is possible using the fabrication techniques of the present invention. In addition, the Sogard and Lentz device includes a polymeric covering fails to teach the possibility of a graft covering formed of a metal or metal-like material as in the present invention. The present specification explains that the graft is "formed as a discrete laminated thin sheet or tube of biocompatible metal or metal-like materials," (page 15, ln. 23-24) which "exhibits improved healing response." Page 8, ln. 17-19. These advantageous, patentable aspects of the present invention was not suggested in the cited art.

Furthermore, references exist that disclose multi-layer stents such as PCT Publication WO 00/54704. Despite such disclosure, the present claims still remain patentable. All that these disclosures provide are descriptions of metal cladded stents that are formed by high pressure, physical stress, and are claimed to typically serve the purpose of adding strength or a radiopaque layer. See first paragraph of Summary of the Invention. Unlike these known devices which are formed via physical manipulation, the present invention is fabricated using metal deposition methodologies as used in microelectronics and non-fabrication vacuum coating arts allowing formation of a "substantially monolithic structure." Furthermore, the metal cladded laminate structures do not disclose or suggest a thin graft layer formed of a metal or metal-like substance. The present invention makes such grafts possible due to the metal deposition methodologies of the present invention. See page 21, ln. 1-5. Such grafts are not possible due to the large stress required to form bonds between layers from post-fabrication manipulation under high pressure as suggest by the reference WO 00/54704.

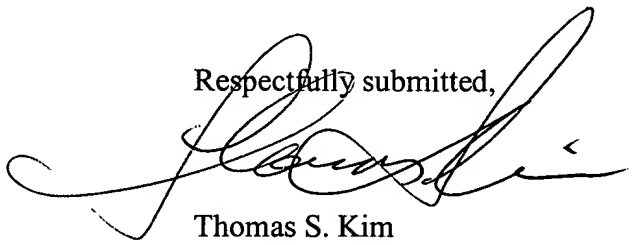
Accordingly, the Applicants respectfully submit that the present claims are in condition for allowance and respectfully request the same.

CONCLUSION

Based upon the foregoing amendments, the pending claims 1, 3-6, 8-18, and 21-25 are suitable for allowance. The Applicants respectfully request such allowance from the Patent Office.

No fee is believed to be due. Should any fee be deemed necessary, however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Rosenbaum & Associates, P.C. deposit account No. 18-2000.

Respectfully submitted,



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May 7, 2003

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VERSION WITH MARKINGS TO SHOW CHANGES

In the claims:

Please cancel claims 2, 7, 19 and 20.

Please amend claims 1, 11 and 16 as they appear below.

Please add claims 21-25 as they appear below.

1. (Amended) An implantable medical device comprising a self-supporting structural member fabricated of a plurality of laminated layers of at least one biocompatible material, wherein the plurality of laminated layers forms a substantially monolithic structure.

11. (Amended) The implantable medical device according to Claim 10, wherein the stent regions further comprises a plurality of structural [member]elements each structural [member]element being comprised of a plurality of laminated layers of a biocompatible material and the graft regions further comprise at least one of the plurality of laminated layers of the biocompatible material forming the structural members of the stent regions.

16. (Amended) [An]The implantable medical graft according to Claim 22, [comprising at least two tubular members concentrically positioned with respect to one another thereby defining an interfacial region between the at least two tubular members, each of] the tubular members being comprised of a plurality of laminated plies forming the tubular member, and a plurality of micro-openings passing through a wall thickness of each tubular member that create cellular migration pathways between a luminal and an abluminal surface of each of the at least two tubular members and through the graft.

---21. (New) The implantable medical device according to Claim 12, further comprising a plurality of openings passing though the graft, the plurality of openings being sized to permit migration of cellular and sub-cellular matter therethrough.

22. (New) An implantable medical graft comprising at least two tubular members concentrically positioned with respect to one another thereby defining an interfacial

region between the at least two tubular members, each tubular member formed from a biocompatible metal or metal-like material.

23. (New) The implantable medical graft according to Claim 22, wherein the biocompatible metal or metal-like material is selected from the group consisting of titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, zirconium-titanium-tantalum alloys, nitinol, and stainless steel.

24. (New) An implantable stent-graft comprising a self-supporting structural member fabricated of a plurality of laminated layers, and a graft member; wherein the self-supporting structural member and graft member are formed from a metal or metal-like material metal or metal-like material.

25. (New) The implantable medical stent-graft according to Claim 24, wherein the metal or metal-like material is selected from the group consisting of titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, zirconium-titanium-tantalum alloys, nitinol, and stainless steel.---

ALL PENDING CLAIMS

1. An implantable medical device comprising a self-supporting structural member fabricated of a plurality of laminated layers of at least one biocompatible material, wherein the plurality of laminated layers forms a substantially monolithic structure.

3. The implantable medical device according to Claim 1, wherein the self-supporting structural member further comprises a stent having a plurality of structural elements.

4. The implantable medical device according to Claim 1, wherein the self-supporting structural member further comprises a graft.

5. The implantable medical device according to Claim 1, wherein the self-supporting structural member further comprises a stent-graft.

6. The implantable medical device according to Claim 1, wherein the self-supporting structural member further comprises a planar film.

8. The implantable medical device according to Claim 3, wherein at least some of the plurality of structural elements further comprise laminated layers of a biocompatible materials selected from the group consisting of titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, zirconium-titanium-tantalum alloys, nitinol, and stainless steel.

9. The implantable medical device according to Claim 4, wherein the graft further comprises a tubular member having a plurality of laminated layers concentrically adjacent to one another, each of the plurality of laminated layers having a plurality of openings passing therethrough of sufficient dimension to permit cellular migration therethrough without permitting fluid flow therethrough.

10. The implantable medical device according to Claim 5, wherein the stent-graft further comprises a tubular member comprising stent regions and graft regions.

11. (Amended) The implantable medical device according to Claim 10, wherein the stent regions further comprises a plurality of structural elements each structural element being comprised of a plurality of laminated layers of a biocompatible material and the graft regions further comprise at least one of the plurality of laminated layers of the biocompatible material forming the structural members of the stent regions.

12. The implantable medical device according to Claim 11, wherein the graft regions subtend interstitial spaces between adjacent pairs of the plurality of structural members.

13. The implantable medical device according to Claim 12, wherein the stent regions further comprise a luminal surface, an abluminal surface and a z-axis thickness and the graft regions have a z-axis thickness less than the stent region z-axis thickness.

14. The implantable medical device according to Claim 5, stent-graft further comprises a stent comprising a plurality of interconnected structural elements forming a generally tubular member having a luminal surface, an abluminal surface, a proximal end and a distal end, and a graft comprising a film projecting outwardly from at least one of the proximal end and the distal end of the stent and along a longitudinal axis of the stent.

15. The implantable medical device according to Claim 14, wherein the film is everted from the at least one of the proximal end and the distal end of the stent over one of the luminal surface and the abluminal surface of the stent and joined to an opposing one of the proximal end and the distal end from which the graft projects.

16. (Amended) The implantable medical graft according to Claim 22, the tubular members being comprised of a plurality of laminated plies forming the tubular member, and a plurality of micro-openings passing through a wall thickness of each tubular member that create cellular migration pathways between a luminal and an abluminal surface of each of the at least two tubular members and through the graft.

17. The implantable medical graft according to Claim 16, further comprising a plurality of spacing members projecting into the interfacial region thereby maintaining the at least two tubular members in a concentric spaced-apart relationship.

18. The implantable medical graft according to Claim 16, further comprising a plurality of microgrooves in an interfacial region surface of at least one of the at least two tubular members.

21. (New) The implantable medical device according to Claim 12, further comprising a plurality of openings passing through the graft, the plurality of openings being sized to permit migration of cellular and sub-cellular matter therethrough.

22. (New) An implantable medical graft comprising at least two tubular members concentrically positioned with respect to one another thereby defining an interfacial region between the at least two tubular members, each tubular member formed from a biocompatible metal or metal-like material.

23. (New) The implantable medical graft according to Claim 12, wherein the biocompatible metal or metal-like material is selected from the group consisting of titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, zirconium-titanium-tantalum alloys, nitinol, and stainless steel.

24. (New) An implantable stent-graft comprising a self-supporting structural member fabricated of a plurality of laminated layers, and a graft member; wherein the self-supporting structural member and graft member are formed from a metal or metal-like material.

25. (New) The implantable medical device according to Claim 24, wherein the metal or metal-like material is selected from the group consisting of titanium, vanadium, aluminum, nickel, tantalum, zirconium, chromium, silver, gold, silicon, magnesium, niobium, scandium, platinum, cobalt, palladium, manganese, molybdenum and alloys thereof, zirconium-titanium-tantalum alloys, nitinol, and stainless steel.